



Modern Biotechnology: Ethical Issues, Ethical Principles and Guidelines

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ABSTRAK

Bioteknologi moden telah menimbulkan kontroversi yang hebat di seluruh dunia. Bantahan utama merupakan kemungkinan kesan buruknya kepada kesihatan manusia, alam sekitar dan status ketidakaslian teknologi DNA rekombinan. Prinsip umum etika adalah menghargai benda-benda hidup dan perlunya terdapat keseimbangan antara faedah dan kesan buruk akibat sebarang campur tangan manusia ke atas alam kehidupan. Keputusan yang berasaskan etika perlu mengambil kira dua jenis pengadilan: fakta (berdasarkan bukti-bukti saintifik dan teori) dan etika (berdasarkan teori-teori falsafah moral yang bersesuaian). Sains cuba memahami apa yang berlaku di dunia ini terutamanya hubungan sebab-akibat yang membentuk kehidupan sementara etika berkaitan dengan apa yang patut kita buat atau sebaliknya. Prinsip-prinsip etika menyediakan garis panduan untuk menilai pelaksanaan sesuatu dasar. Penentuan mengenai apa yang sepatutnya dilaksanakan akan dibuat setelah menimbang faedah sesuatu teknologi seperti kejuruteraan genetik berbanding kemungkinan bahayanya. Walau bagaimanapun, sebarang keputusan berasaskan etika yang melibatkan modifikasi genetik telah terbukti amat mencabar kerana melibatkan begitu banyak aspek kehidupan yang merangkumi aspek individu, perubatan, alam sekitar, politik, perniagaan, haiwan, etika saintifik dan juga agama. Dalam kertas ini isu-isu bioteknologi moden, prinsip etika yang bersesuaian dan garis panduan bagaimana menangani isu-isu etika bioteknologi moden akan dibincangkan.



INTRODUCTION

Scientists have used biotechnology for centuries to enhance the production, availability and quality of food and medicine. Some conventional biotechnology techniques that has been documented for decades includes the use of microorganism in fermentation to make bread, wine or applying rennin to make cheese (Propst 1996; FAO 2001). However within recent times, the development of modern biotechnology has involved powerful new techniques better known





as Molecular Biology that allows scientists to tackle the previous goals with more finesse and speed such as recombinant DNA and genetic engineering, cell fusion, bioprocess and structurally-based molecular design. Given that the technology is new, has immense potential, is rapidly developing, and can be applied to all living beings, it can be used for beneficial purposes but there are also risks (Macer 2006). It is a sophisticated technology that needs advanced laboratory facilities and particular environmental conditions that require investment. Modern biotechnology has been particularly successfully used and applied in food, agriculture, medicine and pharmacy.

Because modern biotechnology is still considered as a new technology and the advancement in these areas have been so rapid, it has been the object of some doubts, fears, concerns as well as an intense and divisive debate worldwide on the potential risks to human health, the environment and society. Modern biotechnology has been classified as a complex emerging issue that exhibits high salience combined with limited knowledge on part of the public. Jacques Diouf, the FAO Director-General, in the foreword of the FAO Ethic Series (FAO 2001), mentioned that technological advances and organizational changes affecting food and agriculture systems over the past years have been both radical and rapid; their repercussions, however, will be felt for a long time to come and, in many cases, the consequences may be irreversible. Science continues to broaden our horizons, offering us new options that invariably give rise to controversy. The introduction of genetically modified organisms (GMOs) into the environment has become highly controversial worldwide. Many consumer, environmental groups and some scientists (Bernauer & Meins 2001; Regal 1994; Ho 1998/1999; Fagan 2000) have voiced strong concerns over the immediate and long term effects of GMOs on human health and environment. Broader social, ethical, religious, and economic issues associated with biotechnology has also been raised (Thompson 1997; BABAS 1999). According to Batalion (2000), the central problem underlying biotechnology is not just its short-term benefits and long term drawbacks, but the overall attempt to 'control' living nature on an erroneous mechanistic view. We as human have conscience and religious belief. Many religions do not allow unrestricted interference with life such as genetic engineering (Epstein 1998). The pace of discovery in genetic-based biotechnology is very rapid and there is anxiety that a kind of technological compulsion ('if we can do it, let's do it') will drive developments ahead of proper ethical consideration of their propriety (Polkinghorn 2000). In this paper several ethical issues related to modern biotechnology, key ethical principles and guidelines on how to address the ethical issues related to modern biotechnology will be discussed.



ETHICAL ISSUES

Basic categories of moral or ethical concerns regarding modern biotechnology fall into two classes: intrinsic and extrinsic (Comstock 2000; Hamid 2000).

EXTRINSIC CONCERNS

Extrinsic objection refers to the concerns regarding the application of the technologies such as the possible risks of different application of biotechnology, consumer's right and patenting issues. All these issues need to be addressed as they have far-reaching consequences on the safety of human, environment and society.

ENVIRONMENTAL CONCERNS

GMOs are 'novel' products which have the potential to reduce or change nature's biodiversity (BABAS 1999; Phillips 1994; Third World Network 1995) or to upset the balance of nature perhaps in unintended ways (FAO 2001). For example, the environmentalists are concerned about the possibility of GM crops having herbicide or insecticide resistance to cross-pollinate with wild or related species, and unintentionally create hard-to-eradicate super-weeds respectively (Hails 2000; Kaiser 1999). There is also concern on the possibility of horizontal gene transfer of transgenic DNA and the potential to create new viruses and bacteria that cause diseases (Hails 2000; Phillips 1994; Ho 1998/1999). Certain genetic alteration in animal or plant pathogens have led to enhance virulence and increased resistance to pesticides and antibiotics (NAS 1987) and the potential of GMOs to harm non-target organisms have been reported (Hails 2000; Goldberg & Tjaden 1990; Ho 1998/1999).

On the other hand, the producers of GMOs claimed that their products did not harm the environment but the fact that the risk assessment studies were carried out by those with vested interests, the results have been questioned. At the moment, the focus of scientists everywhere has been on the development of new biotechnology products. Little efforts have been spent on independent risk assessment studies other than those carried out by the producers. There is a need for more comprehensive and long term studies on the impact of GMOs on the environment.





SOCIOECONOMY

The social impacts of biotechnology in agriculture and food production have been classified into three major categories (Thompson 1997; BABAS 1999):

1. Impacts on small farms. The most debated ethical issue in this context concerns the possibility of market monopoly by big companies and threatening the survival of small farms.
2. Impacts on the economies of developing countries. Many authors have forecast serious impacts on rural economies of the developing countries with a redistribution of benefits from small to large and better-off farmers, according to the same pattern predicted for the industrialized world.
3. Impact on scientific community. Many authors have predicted that increasing commercialization of science would shift the focus of research from publicly beneficial objectives to more profitable corporate activities. These raised ethical concerns about scientific purity, the social function of science and public trusts in scientists (Thompson 1997). However, these concerns are not restricted to food biotechnology.



Some of these concerns have become realities. It is common knowledge that most of the commercialized GM crops were dominated by a few giant companies based in developed countries and many scientists are receiving grants from industries. These situations need to be addressed by governing bodies at the international and national levels to make sure the benefits of modern biotechnology products be made accessible to all regardless of economic status and the scientific purity of research is maintained.



SCIENTIFIC UNCERTAINTIES

Scientists do not agree about the possible consequences of genetic engineering to ecosystems, health and environment (van Dommelen 1999) while several others have acknowledged the possible risks of GMOs to human health and environment (Fagan 2000; Manual for Assessing Ecological & Human Health of Genetically Modified Organisms 1998; Ho 2001). Some analysts have also recognized the inadequacies of scientific risk assessment as a means of predicting and assessing the likely consequences of new technologies (Van Dommelen 1996; Wynne 1992; Stirling 2000). According to Wynne (2002), the institutionalized expressions of the precautionary principle explicitly accommodate recognition of scientific uncertainty as a problem - 'where there is





scientific uncertainty, the precautionary principle may be applied' (UK Government 2001). This principle recognize the possible need to intervene to protect the environment or health in cases when there is scientific uncertainty about the harmful effects of whatever process in question. This is because the 'theoretical harm' of GMOs release into the environment, if it did occur, would be very extensive, perhaps delayed, costly and difficult or impossible to remedy (Heinemann 1997; Ho 1998/1999; Epstein 1998).

Looking at the endless divisive debate and limited independent information on the safety of GMOs worldwide, these scientific uncertainties are real and need to be addressed in a realistic manner. This can be done by first of all acknowledging the existence of scientific uncertainties followed by giving independent risk assessment studies the same priority as product development studies.

CONSUMER'S RIGHT TO FOOD SAFETY AND INFORMATION

Basic consumer claims concerning GM food are about the rights to health to be informed and to choose (BABAS 1999). The first one refers to food safety and the right of consumers to have their health protected from possible hazards derived from eating GM food. Three main areas of concerns area: toxicity, allergenicity and nutritional value. The second issue is the right of consumers to know the information about the foods offered to them (mainly the natural or GM character of food products and their composition) so that they can make an informed choice. This freedom is important because there are food related religious or cultural belief such as the halal (Muslim dietary rule) and kosher (Jewish dietary rule) practices, as well as vegetarians.

PATENTING

Some of the issues in patenting of GMOs is that patenting which allows big corporations to have monopoly of genetically modified plants and animals violates the sanctity of life (Uzogara 2000). Many critics also oppose the fact that seeds are now regarded as propriety products, moreover with the 'terminator gene' technology which renders the seeds sterile (Koch 1998). The farmers are force to buy new seeds each year from multinational companies instead of sowing seeds from previous years' harvest.





INTRINSIC CONCERNS

Intrinsic objection alleged that the process of modern biotechnology is objectionable in itself. This belief is associated with the unnaturalness claim, changing nature and to play 'God'. People's beliefs about nature play a role in their evaluation of the products of biotechnology (BABAS 1999). They embody values and prescriptions about what is morally right or wrong to do to the natural world. The argument is as follows: 'Nature and all that is natural is valuable and good in itself; all forms of biotechnology are unnatural in that they go against and interfere with nature, particularly in the crossing of natural species boundaries'. In some cases the general moral concerns include a religious dimension when they are accompanied by an underlying set of religious beliefs and principles concerning the relationships between God, nature and human beings (BABAS 1999). The central problem underlying biotechnology is not just its short term benefits and long term drawbacks, but the overall attempt to 'control' living nature on an erroneous mechanistic view (Batalion 2000). Many religions does not allow unrestricted interference with life such as genetic engineering (Epstein 1998). In Islam for example, scientific research is encouraged in order to understand natural phenomenon and the universe, and to observe the signs of Allah's glory and ultimately to find the truth (Hajj Mustafa 2001). However, not everything that is applicable is necessarily applicable, it is important to consider fully the purpose and any harmful effect towards human, environment and society and must be in line with the rules of Shari'ah (9th Fiqh-Medical Seminar 2002; Hajj Mustafa 2000). Issues of halal products and sources of genes are also important for the Muslims and the second issue, for the vegetarians too.



KEY ETHICAL PRINCIPLES

There are many ethical traditions or principles proposed by philosophers. Spier (2002) proposed that ethical traditions can be classified into two broad divisions: secular and spiritual. The secular (western) division composed of the many ethical or moral philosophy theories or traditions available while spiritual refers to the religion. Nicholas (2000) suggested two strand of thinking around ethics and life sciences: bioethics and environmental ethics. Each strand of thinking highlights and frame issues in related but different ways.

Majority of philosophers believe that there is no single principle or tradition that should determine our conduct or the making of policies (Nicholas 2000). More than one approach is needed to deal with the range of issues raised by genetic modification. The BABAS report by EFB Task Group on Public





Perception of Biotechnology (1999), The Nutfield Council on Bioethics (1999), Comstock (2000) and Thomas (2001), recommended the use of at least three different theories to make decision on GMOs related issues. The three most common theories or principles relevant to GMOs are the rights theory, utilitarianism and the theory of justice. Nicholas (2000) also suggested the use of those theories under the bioethics branch. Nutfield Council on Bioethics (1999), and Thomas (2001) also highlighted the need to consider environmental ethics as well. Another important principle that should be considered is the Precautionary Principle that have been incorporated into the Rio Declaration as Principle 15 and have been rectified by most countries (BABAS 1999; Nutfield Council on Bioethics 1999). Besides the earlier mentioned theories and principles, another important tradition that need to be seriously considered is the religious or spiritual aspects and cultural values of people in certain country (Gunn & Tudhope 2001; Hamid 2000). Some of the principles which are relevant to GMOs are described below:

RIGHTS THEORY

The basis of this theory: always act so that you treat human beings as autonomous individuals, and not as mere means to an end (Comstock 2000). It refers to the right of an individual to make choices about their own life, and not to be subjected to the imposition of others. Some of the earlier right theorists are John Locke and Thomas Jefferson (The Internet Encyclopedia of Philosophy). Beyleveld and Kinderlerer (1995) suggested the use of the ethical standards in the international human rights conventions (which are part of international law), which has been accepted by very widespread consensus worldwide, at the political or regulatory level. There has been many criticisms of the rights theory too whereby the common thread is that rights doctrines are in some way excessively individualistic (Stanford Encyclopedia of Philosophy).

THEORIES OF JUSTICE

Theories of justice such as utilitarian, libertarian, communitarian or egalitarian are engaged in various ways with the question of the basis on which to distribute resources-on the basis of need, effort, contribution, merit, or the free market (Nicholas 2000). One of the most influential philosopher of the late 20th century is John Rawls, who develop his theory of justice by using both utilitarian and liberty principle (Kay 1997). According to Oyeshile (2008), the plausibility of Rawls' maximin principle lies in the fact that social harmony is indispensable in





maintaining social order. The society has to operate with such principles of justice that cater for the well being of the less fortunate members of the society. Oyeshille (2008) further argued that the problems with that principle is not withstanding but it is a useful axiom for the egalitarian society.

CONSEQUENTIALISM AND UTILITARIANISM

Consequentialism argues that one knows what is the appropriate action, not on the basis of universal duty, but rather on the basis of the outcomes of one's actions (Thomas 2000). This approach is frequently assumed in discussions of biotechnology, such as those around risk and benefit - it is the consequences of the use of a biotechnology that are seen as important, rather than any pre-existing understanding of one's duty or the appropriateness of maintaining a given set of relationships. Thus, a consequentialist would not be concerned with moving genes across species per se, but would judge the appropriateness of that decision on the basis of the possible or likely outcomes of doing so. Although consequentialism is one of the most influential moral theories that can guide our actions, some claim that consequentialism lacks moral values. Mc Elwee (2009) argued that consequentialism limits itself to claims expressed in terms of reasons of action or the comparative value of actions, and eschews altogether the traditional moral categories of wrongness, permissibility and obligation.

PRECAUTIONARY PRINCIPLE

This principle can be thought of as a simple welfare theory (Nicholas 2000). In light of the unknown and unpredictable consequences and risks of biotechnology, opponents argue that regulatory policy should approach biotechnology from the stance of the precautionary principle. With the precautionary principle as the default mode of regulation, regulatory policy should evaluate biotechnology for its human health, animal health, environmental, social, economic, cultural, ethical, and communitarian impacts (Draft Negotiating Text 1998). In other words, opponents of biotechnology insist that the regulation of biotechnology be a technology assessment, not a product regulation.

The precautionary principle has four components while others argue that the precautionary principle must be strengthened by adding four additional components (BNA 1999; Kershen 1999):



1. Taking precaution in the face of scientific uncertainty.
2. Exploring alternatives to harmful actions.
3. Placing the burden of proof on proponents of an activity or product rather than on victims or potential victims of the activity.
4. Using democratic processes to carry out and enforce the principle, including the public right to informed consent.
5. Precaution must be the default mode of all technological decision making.
6. Past technological decisions must be re-examined and reformed, if needed.
7. Precaution demands that the mode of regulation fits the scope of the threat.
8. Society must identify and accommodate itself to broad patterns in ecological processes.

I strongly propose that this principle be adopted in the present situation whereby adequate and independent risk assessments are still limited. If sound, complete and independent risk assessment studies are fully available in the future, then the use of this principle can be made optional.



ENVIRONMENTAL ETHICS



Environmental ethics draws deeply on our understandings of 'nature' and of 'creation', for which every culture has its myths and worldviews (Nicholas, 2000). This is an area where, in contrast to 'bioethics', there is a significant and explicit input from spiritual/ religious traditions. Generally, two broad approaches of environmental ethics can be discerned (Nicholas 2000). Some approaches are human-centred; the environment is valued for what it can provide for humans, and we protect it so that the resources will be there for our use and that of future generations. In the ecocentric approach, the environment is valued not for what it can give us, but because it has intrinsic value, separate from any value that we may give it. This is a position held by some secular environmental movements, but the same value is expressed in some Christian traditions that see the value of creation as coming from God, with humans merely custodians of it.

Both the ecocentric and human-centred approaches can accommodate a position that recognises that humans are not outside the natural world, but are part of the biosphere, that actions we take that have an impact on the environment will also affect humans, and that our own health and survival requires us to attend to the health and sustainability of the planet. This orientation has been captured in recent decades by the concept of Gaia, which is used both as a





scientific theory and as a spiritual concept. The ethical implications of the Gaia concept can be interpreted in different ways either as the consequential imperative that we must care for the environment to ensure our own survival (which we value), or as the responsibility or duty to care for something entrusted to our care or over which we have some power, and of which we are a part.

RELIGION

The spiritual division refers to religion or the belief of individual or people. Kershen (1999) emphasized that the acceptance and success of biotechnology will be based on the ideological beliefs and the cultural values adopted by individual human beings who, in turn will shape societal beliefs and values. There are principles or guidelines on how should we live and what is the right thing to do in most religions. In Islam for example, the sources of rules are first and foremost is the al-Qur'an, followed by the sunnah or hadith (traditions of the Prophet Muhammad) (Hamid 2000). In facing a problem that is not answered in a straightforward manner by earlier two sources, *ijma'* (consensus) have to be sought collectively from the views of *mujtahid* (Muslim jurists who are competent enough to deduce precise inferences regarding the commandment from the al-Qur'an and sunnah). The use of *Qawaid Fiqhiyyah* (Islamic Legal Maxim) to achieve the syariah's objective is also useful and relevant to strengthen the earlier verdict (Mohamad Akram 2006).



ADDRESSING ETHICAL ISSUES OF MODERN BIOTECHNOLOGY

Ethically justifiable conclusions depend on two kinds of judgements: factual (based on scientific evidence and theories), and ethical (based on the best available moral philosophy theories) (Comstock 2000; Thomas 2001). Decisions on what is right to do will be made after balancing the benefits of a technology like genetic engineering with its potential harms. However, ethical decisions concerning genetic modification has proved to be very challenging because it brings together so many ethical aspects of our life that include personal, medical, environmental, political, business, animal and scientific ethics besides religion.

A method for addressing ethical issues related to modern biotechnology as recommended by Comstock (2000) with several modifications is suitable for use in Malaysia. He suggested working methodically through a series of questions:





WHAT IS THE HARM ENVISAGED?

Describe briefly (a) the harm or potential harm; (b) who are the stakeholders, that is, all of the persons and non-persons (animals, ecosystems, other nonhuman entities) who may be harmed; (c) the extent to which these stakeholders will be harmed; and (d) the distribution of harms (are those at risk of being harmed the same or different from those who may benefit?).

A technology is acceptable if it creates an acceptable set of consequences for every member of society (Fischhoff 1999). So in order to determine acceptable risk-benefit tradeoffs, it may be useful to ask or survey a properly chosen sample of citizens to study their attitude and acceptance towards the tradeoffs. The Malaysian stakeholders in the Klang Valley for example were more supportive of GM palm oil (modified to reduce its saturated fat) and GM insulin compared to GM soybean (resistant to herbicide) (Latifah et al. 2009). In Islam, the analysis of risk-benefit related to modern biotechnology is provided under the *Maqasid Syariah* principle.

WHAT INFORMATION DO WE HAVE?

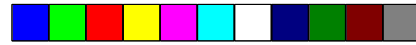
Sound ethical judgments go hand-in-hand with thorough understanding of the scientific facts. In a given case, we may need to ask: (a) Is the scientific information about harm being presented reliable, or is it fact, hearsay, or opinion? (b) What information do we not know that we should know before making the decision?

In the case of modern biotechnology products, there is limited information on their safety. This scenario stresses the need for more balanced approach by scientists and governments in giving equal importance to independent risk assessment studies besides product development.

WHAT ARE THE OPTIONS?

In assessing the various courses of action, emphasize creative problem-solving, seeking to find win-win alternatives in which everyone's interests are protected. Here we must identify (a) what objectives each stakeholder wants to obtain; (b) how many methods are available by which to achieve those objectives; (c) what are the advantages and disadvantages of each alternative?

In case of conflict between several options, Josephson Institute (Svatos 2000) recommended that the option which presents an ethical value (such as trustworthiness, respectful, responsible, fair, caring, civic virtue) is chosen compared to non-ethical values (such as money, power). For example, the



company Pioneer Hi-Breed has chosen an ethical option by withdrawing its products, GM peanuts (which contain a gene from Brazilnut) which has been found to be allergenic despite having invested much money on the development of the GM peanuts (Nordlee et al. 1996).

WHAT ETHICAL PRINCIPLES SHOULD GUIDE US?

Since ethical theorists are divided about which theories is best, and each principle has its own strengths and weaknesses, I agree with the suggestion by Comstock (2000) to use at least three most common principles relevant to modern biotechnology, one by one. Should all three principles converge on the same conclusion, then there is good reason to think that the conclusion is morally justifiable.

However, I strongly recommended the use of additional theories/principles such as environmental ethics as highlighted by the Nutfield Council on Bioethics (1999) and Thomas (2001), and the Precautionary Principle (BABAS 1999; Nutfield Council on Bioethics 1999). I also strongly agree with the proposition by Gunn and Tudhope (2001) and Hamid (2000) that the religious or spiritual aspects and cultural values of people need to be seriously considered especially in multi-ethnic and multi-religion country such as Malaysia.

In Malaysia since the majority of the citizens are Muslims and the official religion is Islam, Divine law should be used as the moral basis for law and society (Hamid 2000; Majdah 2001). The prohibitory status of modern biotechnology applications should be studied case by case and in line with the Islamic principles. In Islam, the sources of rules are first and foremost is the al-Qur'an, followed by the sunnah or hadith (traditions of the Prophet Muhammad) (Hamid 2000). In facing a problem that is not answered in a straightforward manner by earlier two sources, *ijma'* (consensus) have to be sought collectively from the views of *mujtahid* (Muslim jurists who are competent enough to deduce precise inferences regarding the commandment from the al-Qur'an and sunnah). The last source of guideline for the Muslims is *aq'il* (reasoning). Issues of halal is also very important for Muslims (BABAS 1999). The acceptance of modern biotechnology applications by other major religions in Malaysia such as Buddha, Hindu and Christian should also be considered.

HOW DO WE REACH MORAL CLOSURE?

Does the decision we have reached allows all stakeholders either to participate in the decision or to have their views represented? If a compromise solution is



deemed necessary in order to manage otherwise intractable differences, has the compromise been reached in ways that has allowed all interested parties to have their interests articulated, understood, and considered? If so, then the decision is justifiable on ethical grounds.

For example before the start of large scale production of a biotechnology product or even better at the product development stage in Malaysia, the views of relevant stakeholders such as the representatives of the consumers, the industries, the religious scholars of major religions in Malaysia, policy makers and the scientists be sought. If all stakeholders agree on a certain decision whether to support, reject or delay decision for certain valid reasons such as to gather more information, the relevant authorities in Malaysia have to abide by the decisions.

CONCLUSION

Modern biotechnology if applied responsibly, have vast potential to benefit mankind and the environment. At the same time, the speed of genetic change by genetic engineering may represent a new potential and unexpected impact on biosphere (FAO 2000). It is not possible to make sweeping generalizations about modern biotechnology; each application must be fully analyzed on a case-by-case basis. Through complete and transparent assessments (scientifically and ethically) of modern biotechnology applications, and recognition of their short and long term implications towards human, environment and society and acknowledging scientific uncertainties and taking possible precautionary measures, only then, the controversies can be less contentious and more constructive, and the full benefits of modern biotechnology may be maximized. Ethical guidelines regarding the status of modern biotechnology applications in Malaysia should be in line with the Islamic principles as well as the consideration of the acceptance by other major religions in Malaysia.

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